Analysis

Double Patenting Rejections

Applicant defers discussion of this issue until the claims of the present application have been allowed. If necessary, terminal disclaimer(s) will be submitted.

103 Rejections

Claims 1, 5, 6, and 8-13

The rejection of claims 1, 5, 6, and 8-13 over Müller in view of Thanoo is respectfully traversed. Claim 1 recites a microparticle formed from macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups. The dependent claims specify characteristics about the macromers, the method of crosslinking the macromers, and additional characteristics of the microparticles.

Neither Müller nor Thanoo teaches or suggests microparticles formed from macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups.

Müller teaches that the macromers (prepolymers) can be used to make mouldings- devices formed by placing the macromers in a mould and crosslinking the macromers. The articles formed are shaped like the mould. See column 14, lines 50-64 of Müller.

> The novel prepolymers can be converted into mouldings, in particular contact lenses, in a manner known per so, for example by carrying out the crosslinking of novel prepolymers in a suitable contact-lens mould. The invention therefore furthermore relates to mouldings essentially comprising a novel crosslinked polymer. Further examples of novel mouldings, besides contact lenses, are biomedical mouldings and mouldings for specifically ophthalmic purposes, for example intraocular lenses, eye bandages, mouldings which can be used in surgery, such as heart valves, artificial arteries or the like, furthermore films and membranes, for example membranes for diffusion control, photostructurable films for information storage, and photoresist materials, for example membranes and mouldings for etch resists and screen printing resists.

Microparticles are not made using a moulding process. A mould is not used to shape the particles- they are "free formed" using a method such as suspension polymerization, for example. See page 21-22 of the application for a description of possible methods for making microparticles from macromers.

Thanoo teaches microspheres formed by polymerizing PVA with glutaraldehyde. He does not start with a prepolymer (macromer) - i.e. a polymer having crosslinkable groups. Glutaraldehyde crosslinked PVA particles have been used for a number of years as an embolic agent. Thanoo teaches a similar material- formed into microspheres rather than irregularly shaped particles. A particular drawback of glutaraldehyde crosslinked PVA is that it forms tough, water insoluble particles (see *Billmeyer, F.W. Jr; 'Textbook of Polymer Science', John Wiley & Son, Inc. Singapore, pp 391-395, 1984).* The microspheres taught by Thanoo are very different from the claimed microspheres. For one thing, by using macromers, the use of glutaraldehyde is completely avoided and the resulting microspheres do not have residual glutaraldehyde.

Müller alone, or in combination with Thanoo, does not teach or suggest that the prepolymers taught therein can be used to make microparticles.

Claims 39-61

The rejection of claims 39-61 over Müller alone or in view of Lally is respectfully traversed. Claim 39 specifies that the crosslinkable groups of the prepolymer are crosslinked via redox initiated free radical polymerization. Claim 51 specifies that the article is biodegradable.

Applicants do not disagree with the Examiner's assertion that Müller teaches free radical initiated polymerization. But the Examiner does not address the Applicant's claims- that the free radical initiation is **redox initiated**. Neither Müller nor Lally teaches or suggests that the prepolymers are crosslinked via redox initiated free radical polymerization. Both teach that the crosslinkable groups are crosslinkable via "photocrosslinking, thermal crosslinking or 2+2 photocyclodimerization." (See Müller at column 12, lines 52-53.) The preferred method is photocrosslinking, which generally requires the use of a photoinitiator and the crosslinking is initiated by actinic or ionizing radiation. (See Müller at column 12, lines 54-60.) Photoinitiation requires the use of an outside influence- a radiation source. Initiation via redox chemistry on the other hand, does not require the use of an outside influence. The system can be self-contained, with the use of a two part system having one part containing the reductant and the other part containing the oxidant. The system can thus be used for applications where it is difficult or otherwise desirable to employ a light source.

Claim 51

Neither Müller nor Lally teaches or suggests a biodegradable medical article formed from macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups. The hydrogels formed from the macromers taught in the cited references are not degradable. Biodegradability is not mentioned as desirable or achievable.

Conclusion

The cited references do not teach or suggest the claimed inventions. Accordingly, it is respectfully submitted that the references are not appropriate as the basis for rejection of the claims.

Respectfully submitted,

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I hereby certify that this paper, along with any paper referred to as being enclosed or attached, is being ~~faxed~~ mailed to the United States Patent and Trademark Office ~~after final fax number 703-305-3592~~ on the date shown below.

Collen A. Beard

April 17, 2003